

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application
of _____

for _____

Inventor(s)

Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Grahek et al.

Application No.: 10/698,009

Group No.: 1626

Filed: October 30, 2003

Examiner: Not yet assigned

For: **Process for Obtaining HMG-CoA Reductase Inhibitors of High Purity**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

(Information Disclosure Statement--page 1 of 8)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is *mandatory*;

Express Mail certification is *optional*.)

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10*

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☐ transmitted by facsimile to the Patent and Trademark Office.

Signature



Timothy M. Murphy, Esq.

Date: February 26, 2004

***WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).
"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will *not* be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

NOTE: The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☒ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ EPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

NOTE : "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Grahek et al. Attorney Docket: 2260/119
Serial No: 10/698,009 Art Group Unit: 1626
Date Filed: October 30, 2003 Examiner Name: Not yet assigned
Invention: Process for Obtaining HMG-CoA Reductase Inhibitors of High Purity

**LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANT'S INFORMATION DISCLOSURE STATEMENT**

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	AA	US 4,231,938	Nov. 4, 1980	Monaghan	260/343.5
	AB	US 5,043,423	Aug. 27, 1991	Viscomi et al.	530/344
	AC	US 5,202,029	Apr. 13, 1993	Haytko et al.	210/656
	AD	US 5,420,024	May 30, 1995	Carta et al.	435/125
	AE	US 5,427,686	Jun. 27, 1995	Asher	210/635
	AF	US 6,268,186	Jul. 31, 2001	Sibeijn et al.	435/125

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Reference Number	Country Code	Document Number	Publication Date	Patentee or Applicant	Class/Subclass
	AG	WO	92/16276	Oct. 1, 1992	Haytko et al.	B01D 15/08
	AH	EP	0 416 416 A1	Mar. 13, 1991	Viscomi et al.	C07K 1/14

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	AI	Horváth	Displacement Chromatography: Yesterday, Today and Tomorrow, Journal of Chromatography Library, Volume 32, pgs. 179-203. 1985
	AJ	Brian Bidlingmeyer (Editor)	Preparative Liquid Chromatography, Journal of Chromatography Library, Volume 38, pgs. 12-13, 1987
	AK	Cramer et al.	Tandem use of Carboxypeptidase Y. Reactor and Displacement Chromatography for Peptide Synthesis, Journal of Chromatography, Vol. 394, pgs. 305-314 (1987)
	AL	Subramanian et al.	Displacement Chromatography of Biomolecules, Journal of Chromatography, Vol. 439, pgs. 341-351 (1988)

	AM	Gu et al.	Displacement Effect in Multicomponent Chromatography, AIChE Journal, Vol. 36, pgs. 1156-1162 (1990)
	AN	Felinger et al.	Optimization of the experimental conditions and the column design partners in displacement chromatography, Journal of Chromatography Vol. 609, pgs. 35-47, (1992)
	AO	Frenz	Frontiers of Biopolymer Purification: Displacement Chromatography, LC-GC International, Vol. 5, pgs. 18-21, (1992)
	AP	Guiochon et al.	Fundamentals of Preparative and Nonlinear Chromatography, pgs. 301-303, Academic Press, © 1994
	AQ	Grahek et al.	Chromatographic Purification of SINEGMG-CoA Reductase Inhibitors, Lek dd. Research and Development
	AR		PCT/IB 99/01553 International Search Report

Examiner Signature: _____

Date Considered: _____

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

Section 4. Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted

NOTE: "A copy of any patent, publication or other information listed in an information disclosure statement is not required to be provided if it was previously cited by or submitted to the Office in a prior application, provided that the prior application is properly identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120." 37 C.F.R. section 1.98(d).

WARNING: "This exception to the requirement for copies of information does not apply to information which was cited in an international application under the Patent Cooperation Treaty." Notice of April 20, 1992 (1138 O.G. 37-41, 38).

WARNING: "Information which is cited or submitted to the Office in the parent application of a file wrapper continuing application under 37 C.F.R. section 1.62 will be part of the file before the examiner and need not be resubmitted in the continuing application. Likewise, the examiner will consider information cited or submitted to the Office in a parent application when examining a continuing application and thus this information need not be resubmitted unless applicant desires the information to be printed on the patent." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

WARNING: While a copy of a non-English language item of information need not be submitted, if it was previously submitted to, or cited by, the Office in a prior application, provided it is properly identified in this statement and this application relies on that earlier filing date under 35 U.S.C. 120, nevertheless, the requirement in section 1.98(a)(3) for a concise explanation of non-English language information would not be satisfied by a statement that a reference was cited in the prosecution of a parent application. The concise explanation must explain the relevance, as presently understood by the person designated in section 1.56(c) most knowledgeable about the content of the information. Notice of January 9, 1992, 1135 O.G. 13-25, at 20.

This application is a continuation-in-part application from US. Patent Application Serial No. 09/720,952, filed January 3, 2001, based on PCT application no. PCT/IB99/01553, which has an international filing date of September 17, 1999, both of which are hereby incorporated by reference herein.

The following references were submitted to, and/or cited by, the Office in the prior application(s) and, therefore, are not required to be provided in this application:

AA -AI, AK-AO, AR

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☒ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

U.S. patent citations are not included pursuant to 37 CFR 1.98 9(a)(2)(i) and 37 CFR 1.491(b), in which the USPTO waived the requirement for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC § 371 after June 30, 2003.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this certification is

(check each applicable item)

(a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

(b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

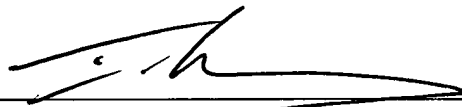
(c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.



SIGNATURE OF PRACTITIONER

Timothy M. Murphy, Esq.
(type or print name of practitioner)

125 Summer Street, 11th Floor
P.O. Address

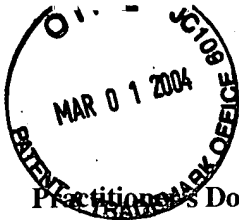
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Customer No.: 002101

2260/119 295391



Patent application Docket No. 2260/119 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application
of _____

Inventor(s)

for _____

Title of invention

OR

In re application of: Grahek et al.

Application No.: 10/698,009

Group No.: 1626

Filed: October 30, 2003

Examiner: Not yet assigned

For: **Process for Obtaining HMG-CoA Reductase Inhibitors of High Purity**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
WITHIN THREE MONTHS OF FILING OR
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. SECTION 1.97(b))

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. SECTION 1.8(a))

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service with
sufficient postage as first class mail in an envelope
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Alexandria, VA 22313-1450

Date: February 26, 2004

FACSIMILE

☐ transmitted by facsimile to the Patent and Trademark
Office.

Signature

Timothy M. Murphy, Esq.

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant: (1) within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

NOTE: The "filing date of a national application" under 37 C.F.R. section 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. section 1.53(b) as "the date on which: (1) A specification containing a description pursuant to section 1.71 and at least one claim pursuant to section 1.75; and (2) any drawing required by section 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by section 1.41." 37 C.F.R. section 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. section 371(c) within the periods set forth in section 1.494 or section 1.495. 35 U.S.C. section 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. section 1.97(b)(2).

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirement (37 C.F.R. section 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. section 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. section 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).



SIGNATURE OF PRACTITIONER

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2260/119 297184